



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/521,334	10/27/2005	Mikhail I Papisov	0492479-0041	1459
24280 7590 04/30/2010 CHOATE, HALL & STEWART LLP TWO INTERNATIONAL PLACE BOSTON, MA 02110				
EXAMINER CHU, YONG LIANG				
ART UNIT		PAPER NUMBER		
1626				
NOTIFICATION DATE		DELIVERY MODE		
04/30/2010		ELECTRONIC		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patentdocket@choate.com  
jhess@choate.com  
lbradley@choate.com

# Office Action Summary

**Application No.**

10/521,334

**Applicant(s)**

PAPISOV ET AL.

**Examiner**

YONG CHU

**Art Unit**

1626

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 06 April 2010.  
2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.  
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-6, 11, 12, 14, 19, 20, 41-51, 54-56, 58, 59 and 63-71 is/are pending in the application.  
4a) Of the above claim(s) 44-51, 54-56, 58 and 59 is/are withdrawn from consideration.  
5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.  
6) ☒ Claim(s) 1-6, 11, 12, 14, 19, 20, 41-43, and 63-71 is/are rejected.  
7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.  
8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.  
10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)  
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-940)  
3) ☒ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date 04/06/2010 and 04/06/2010  
4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_  
5) ☐ Notice of Informal Patent Application  
6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

New claims 63-71 are added. Claims 1-6, 11-12, 14, 19-20, 41-51, 54-56, 58-59, and 63-71 are pending. Claims 44-51, 54-56, 58 and 59 remain withdrawn as non-elected subject matter.

#### ***Information Disclosure Statement***

Applicants' Information Disclosure Statements, filed 04/06/2010 and 04/06/2010, have been considered. Please refer to Applicant's copies of the PTO-1449 submitted herewith.

#### ***Response to Amendment***

The amendment by Applicants' representative Dr. Brenda Herschbach Jarrell dated on 01/15/2010 has been entered.

#### ***Declaration under Rule 37 C.F.R. §1.132***

Applicants' submission of the Declaration under Rule 37 C.F.R. §1.132, filed on 01/15/2010 has been entered.

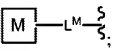
#### ***Response to Arguments/Remarks***

#### **Claim Rejection under 35 U.S.C. §103(a)**

Applicant's 132 Declaration on 01/15/2010, amendment and arguments have been fully considered, but are not sufficient to overcome the rejection. Specifically, the attached 132 Declaration states that at the time the instant application was filed, there is a significant level of unpredictability regarding the reactivity and stability of polyacetals.

In addition, Applicants state that knowing that oxime formations are carried out under acidic conditions (i.e. at pH ~4), it would be apparent that the integrity of acetyl groups of the polymer backbone would be an issue and their reactivity unpredictable, and the stability of PHF-like portions of the main chain would be subject to degradation below pH 7. The synthesis of oxime-forming conditions of PCF or PHF is completely unpredictable. See page 5 of the 132 Declaration on 01/15/2010. To respond to Applicant's arguments, please see the articulations in the previous Office actions. The key argument Applicants made here is that an oxime-containing polyketal and polyacetyl conjugate is not stable under acidic conditions (i.e. at pH ~4) due to the stability of polyacetals or polyacetyls. However, at lines 1-4, paragraph [0279], page 92 of the instant specification, it states that the coupling reaction between the PHF diol and the coupling reagent VII was carried out at pH=3.0 by addition of 1M NaHSO<sub>4</sub> and agitated for 2 hours on the ice. This disclosure clearly contradicts with the statement Applicants made in the instant 132 Declarations, namely an oxime-containing polyketals and polyacetyl conjugate is not stable under acidic conditions. Furthermore, even the polyketals and polyacetals backbone may be partially degraded under acidic condition as suggested by Applicants, the partially degraded polyketal and polyacetal conjugates are still obvious to the instant claims, because the molecular weight of the carrier is defined between about 0.5 and about 1500 kDa according to claim 1. There is no absolute degradation in such way that molecular weight of the resulting polyketals and polyacetals is absolutely below 0.5 kDa (i.e. a completely break down in its backbone). In addition, a claim for chemical compound that reads, in its entirety, "A conjugate

comprising a carrier substituted with one or more occurrences of a moiety having the

structure:  .. polyketals and polyacetals.. and the molecular weight of

the carrier is between about 0.5 and about 1500 kDa;..” is properly construed to encompass any compound meeting that structural definition at any amount without further limitation. For the legal interpretation of a compound claim, see *SmithKline Beecham Corp. v. Apotex Corp.*, U.S. Court of Appeals, Federal Circuit, (2005), 403 F3d 1331. Finally, the 132 Declarations are inventors’ opinions; there is not side-by-side fact based data comparison to support the argument. Therefore, the 103(a) rejection is maintained.

**New claims 63-71**

New claims 63-71 are also rejected under 103(a) for the same reason, as articulated above.

**Specification**

Specification is objected to for containing the information may subject to copy right violation if allowed. Specifically, the text on pages 110-138 of the specification is copy of a technical manual from Pierce Chemicals, Inc.

***Conclusions***

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

#### ***Telephone Inquiry***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yong Chu, *Ph.D.*, whose telephone number is 571-272-5759. The examiner can normally be reached on 7:00 am - 3:30 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph K. M<sup>2</sup>Kane can be reached on 571-272-0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Status Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR.

Art Unit: 1626

Status information for unpublished applications is available through Private PAIR only.

For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Yong Chu/  
Primary Patent Examiner  
Art Unit 1626